ADDITIONAL GUIDANCE: FORMAT AND RISK CHARACTERIZATION EFED ENVIRONMENTAL RISK ASSESSMENT DOCUMENTS

The purpose of EFED SOP #0001 is to provide guidance to EFED risk assessors on preparing EFED's Environmental Risk Assessments for Registration Eligibility Documents (REDs), New Active Ingredients and Section 3 Registrations for New Uses of Old Chemicals. This guidance is not intended to address the risk assessments prepared by EFED to support Section 18 or 24(c) activities.

Provided below is a generic environmental risk assessment outline, which provides guidance to scientists developing EFED risk assessments. **(Note: Inclusion of a Table of Contents in the risk assessment may be helpful to the reader so that information can be more easily found. Risk Assessors should consider the length and complexity of the document in determining the need to develop a Table of Contents. In addition, the Human Health Drinking Water Assessment is not covered in this guidance. Separate guidance needs to be prepared for this EFED assessment)**

Generic Environmental Risk Assessment Outline

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7.1.1. Risk Mitigation Measures

Appendices
(written for a scientific audience) may include:

- Hazard Data (includes sediment tox, endocrine disruption data, if relevant)
- Environmental Fate Data
- Detailed Modeling Discussion
- Detailed Water Monitoring Discussion
- Detailed Risk Quotient Calculations

- Incident Lists
- Detailed Endangered Species Analysis

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General Guidance Especially for the Executive Summary (1.0) and the Risk Characterization (6.0)

Agency policy requires that risk characterizations be prepared in a manner that is *clear*, *transparent*, *reasonable*, and *consistent* with other risk characterizations of similar scope. Thus, the following suggestions:

For clarity:

- ☞ Be brief; avoid jargon.
- ☞ Make language and organization understandable to risk managers and the informed lay person.
- ☞ Fully discuss and explain unusual issues specific to a particular risk assessment.

For transparency:

- ☞ Identify the scientific conclusions separately from policy judgments.
- ☞ Clearly articulate major differing viewpoints of scientific judgments.
- ☞ Define and explain the risk assessment purpose (e.g., regulatory purpose, policy analysis, priority setting).
- ☞ Fully explain assumptions and biases (scientific and policy).

For reasonableness:

- ☞ Integrate all components into an overall conclusion of risk that is complete, informative, and useful in decision making.
- ☞ Acknowledge uncertainties and assumptions in a forthright manner.
- ☞ Describe key data as experimental, state-of-the-art, or generally accepted scientific knowledge.
- ☞ Identify reasonable alternatives and conclusions that can be derived from the data.
- ☞ Define the level of assessment (e.g., screening, extensive field data, probabilistic) along with the reason(s) for selecting this level of effort.
- ☞ Explain the status of peer review.

For consistency with other risk characterizations:

- ☞ Describe how the risks posed by one pesticide use compare with the risks posed by a similar pesticides and uses or under similar application methods and use conditions.
- ☞ Indicate how the strengths and limitations of the assessment compare with past.

REVIEWER GUIDANCE BY OUTLINE ITEM

Under each of the elements presented, questions are provided to help direct the risk assessor. These questions are not meant to be all encompassing, nor does every question apply to all scenarios or risk assessments; they are meant as a guide. The risk assessor should consider the unique aspects of his/her risk assessment in considering the questions posed below, and may want to expand into other areas for more complex or unique situations.

1.0 Executive Summary [See Attachment A for an example]

The risk assessment executive summary is intended to be a **brief** synopsis of the key factors in the risk assessment. The summary is not intended to simply repeat verbatim portions of the risk assessment itself, but to provide a very concise summary of the most significant details of the risk assessment with emphasis on the uniqueness of the chemical. (Note: Sub-headings may be useful here to help the reader follow the discussion.) The following elements should be addressed in the executive summary:

- *What is this chemical, it's use sites and how is it applied?*
- *How does this chemical work; the mode of action ?*
- *What assessment endpoints were chosen for risk assessment? Why?*
- *What are the effects seen and are they of concern?*
- *Which organisms are at risk? Do we have tests on these organisms or do we have to extrapolate from test species?*
- *What are the major risk concerns and what is the best scale for the assessment?*
- *What routes of exposure to this chemical were considered in the risk assessment?*
- *What types of risk assessments were conducted?*
- *Where (locations, areas, etc) and when will the risks likely to occur?*
- *Are the effects seen across different species?*
- *What are the magnitude and probability of these effects?*
- *Will the effects influence the density and diversity of the species?*
- *How certain/uncertain are the scientists in the assessment predictions? Explain.*
- *Were there any incidents or field studies to support/confirm the estimated risks?*
- *Will there be population impacts, what are the extent and significance of these impacts, and will the population recover?*
- *What models were used, are they widely accepted and scientifically sound, how predictive are they, and have they been validated?*
- *Help put this pesticide and its potential environmental risk in perspective. What are*

the results of your comparative analysis with similar pesticides and/or alternatives and tell us how the results fit into the overall risk picture for the pesticide in question?
➔ *Identify any mitigation measures that will eliminate or reduce the calculated risk and discuss how certain you are that these mitigation measures will work.*
➔ *What are the data gaps which should be considered by the regulatory manager and what regulatory decisions do the data support?*

2.0 Pesticide Characterization [See Attachment A for an example]

2.1. Physical/Chemical Properties Characterization

➔ *What is the identity, chemical class, and molecular structure of the compound?*
➔ *What are the known physical/chemical properties of this compound (include as a list)? Are there any isomeric forms of the chemical? Are there any impurities of known toxicological concern (e.g., nitrosamines, dioxins, etc.).*
➔ *What do the vapor pressure or solubility properties indicate about the behavior of the chemical related to nontarget aquatic and terrestrial organism exposure patterns?*

2.2. Pesticide Type, Class, Mode of Action

➔ *What is type of pesticide (insecticide, fungicide, herbicide, etc.)?*
➔ *What is class of pesticide?*
➔ *What is mode of action of the pesticide?*

3.0 Use Characterization [See Attachment A for an example]

➔ *What is the use or potential use distribution: acreage and geographic distribution of relevant crops?*
➔ *What is the amount and geographic distribution of pesticide use in recent years?*
➔ *What is the use history?*
➔ *What are any geographic limitations on use from the registered label?*
➔ *What are the use patterns: application method(s);site(s) of application (foliar, soil surface, soil incorporated, etc.)?*
➔ *What are the type(s) of formulation?*
➔ *What are the crop cultural practices, irrigation practices, weather patterns?*

4.0 Analysis Plan [See Attachment A for an example]

The characteristics of an ecological risk assessment are directly determined by agreements reached by risk managers and risk assessors during early planning meetings.

These agreements are the products of planning. They include (1) clearly established and articulated management goals, (2) characterization of decisions to be made within the context of the management goals, and (3) agreement on the scope, complexity, and focus of the risk assessment, including the expected output and the resources available to complete it.

4.1. The Regulatory Goal

➔ *What are the management goals and decisions needed, and how will risk assessment help?*

➔ *Are there any policy considerations that everyone should be aware of?*

➔ *What precedents are set by similar risk assessments and previous decisions?*

➔ *What is the context (the spatial and temporal boundaries) of the assessment (e.g., agricultural use site 2X per season -June and July, aquatic habitat adjacent to the use site, etc.)?*

➔ *What resources in EFED, RD/SRRD, BEAD are available?*

➔ *What precedents are set by similar risk assessments and previous decisions?*

➔ *What level of uncertainty is acceptable?*

4.2. Define the Assessment Endpoints

Assessment endpoint selection and rationale should include a discussion of the strengths and weaknesses in the doses and endpoints selected relative to the exposure routes, exposure durations and if appropriate, the populations being assessed and risk assessments being conducted.

➔ *What are the specific assessment endpoints? What is the rationale?*

➔ *What is the state of knowledge of these endpoints?*

4.3. Describe the Measures of Effect

➔ *What are the critical measures of effect that characterize the assessment endpoints? (Discuss their availability and appropriateness)*

➔ *What are the potential constraints (e.g., limits on expertise, time, available methods and data)?*

➔ *What is the characterization of the dose-response curve (steep, shallow or flat)?*

➔ *How well do the data fit the exposure scenarios being evaluated?*

➔ *What level of confidence do we have in the data we are using (are there outstanding hazard studies that would better characterize the endpoint or the dose response curve, or*

should be performed by a more appropriate route)?
➔ *Is there any evidence of endocrine disruptor effects?*

4.4. Describe the Measures of Exposure

➔ *What are the critical measures of exposure that characterize the assessment endpoints? (Discuss their availability and appropriateness)*
➔ *What are the potential constraints (e.g., limits on expertise, time, available methods and data)?*

4.5. Discuss the Level of Risk Characterization Needed

➔ *What level of risk characterization will be required to achieve the regulatory goal(s)(screening level; screening level plus field data on effects/exposure and incidents; probabilistic risk assessment methods plus field data on effects/exposure and incidents)?*
➔ *What are the resources required and the potential constraints for the level of risk characterization required?*
➔ *Is recovery an issue? If so, how likely is it and how long will it take?*

5.0 Analysis

Analysis is a process that examines the two primary components of risk, exposure and effects, and their relationships between each other and site characteristics. The objective is to provide the ingredients necessary for determining or predicting ecological responses to pesticides uses under exposure conditions of interest. The products of analysis provide the basis for estimating and describing risks in risk characterization.

5.1. Characterization of Ecological Effects

This is not intended to simply be a listing of the LC50, LD50, NOAEL/LOAELs and effects from each study or a shortened version of the executive summaries. Characterization of Ecological Effects is intended to provide a comprehensive look at the overall toxicity of a chemical. Each of the following questions do not need to be specifically answered as asked, but they are intended to provide the assessor guidance on the types of questions the characterization of ecological effects should address. This section of the risk assessment should highlight and identify key effects information from the ecological effects chapter in the appendix, **not to reiterate the chapters in their entirety**.

5.1.1. Aquatic Hazard Characterization

➔ *Does the aquatic data clearly define the toxicity of the chemical? Are the toxic effects typical of this class of compound (e.g., organophosphorous ChE inhibition)? Are the observed effects unique to the chemical class?*

➔ *What are the type and extent of available ecological effects information (e.g., field surveys, laboratory tests, or structure-activity relationships)?*

➔ *What are the toxicologically-significant adverse effects? Do these effects occur among all tests and test species? At what dose levels did these effects occur? Is there a causal (dose-response) relationship between the effects and the doses tested?*

➔ *Does the chemical cause reproductive effects and do the effects occur above, at, or below estimated environmental residue levels?*

➔ *Are there any critical data gaps?*

➔ *Is there any evidence of "endocrine disruption?"*

➔ *Have significant degradates/metabolites of concern been identified? What is known or can be predicted about the toxicity of the metabolites and how does the toxicity compare to the parent (less, the same or greater than the parent)? Are the metabolites to be considered for regulatory and risk assessment purposes?*

➔ *What are the strengths, limitations, and uncertainties of the aquatic data?*

➔ *What are the aquatic measures of effect data that specifically characterize the aquatic assessment endpoint(s) previously identified? (e.g., test results on two species of fish are being used to represent the toxicity to all aquatic vertebrates; further, the preliminary risk estimation will use the LC50 of the most sensitive species)*

➔ *If extrapolations are used, how appropriate are they? (.e.g., acute to chronic; extrapolations from lab to field; extrapolations from single species laboratory data to other trophic levels or indirect effects)*

➔ *What are the toxicity values (range, if appropriate), slopes, and confidence intervals, for the species/representative group chosen for the assessment?*

➔ *If the toxicity data was analyzed or used in a distribution, explain why and how.*

➔ *Be sure to identify the most sensitive species for each endpoint, the specific effect observed for each NOEC, any secondary effects, potential food source impacts.*

➔ *What is that adequacy and quality of the data (from both a scientific and regulatory perspective)?*

➔ *What are any data gaps and value of additional information to the risk assessment?*

➔ *What is the relationship of the species tested to species and habitat where exposure is likely to occur?*

➔ *What is the relevance of field study and/or monitoring data and incidence data?*

➔ *What is a synthesized interpretation of all available data including lab and field?*

5.1.2. Terrestrial Hazard Characterization

➔ *Does the terrestrial data clearly define the toxicity of the chemical? Are the toxic effects typical of this class of compound (e.g., organophosphorous ChE inhibition)? Are the observed effects unique to the chemical class?*

➔ *What are the type and extent of available ecological effects information (e.g., field surveys, laboratory tests, or structure-activity relationships)?*

➔ *What are the toxicologically-significant adverse effects? Do these effects occur among all tests and test species? At what dose levels did these effects occur? Is there a causal (dose-response) relationship between the effects and the doses tested?*

➔ *Are there dermal and inhalation toxicity studies available? Do they show the same or different toxic effects? Do the toxic effects occur at the same or different dose ranges?*

➔ *Does the chemical cause reproductive effects and do the effects occur above, at, or below estimated environmental residue levels?*

➔ *Are there any critical data gaps?*

➔ *Is there any evidence of "endocrine disruption?"*

➔ *Have significant degradates/metabolites of concern been identified? What is known or can be predicted about the toxicity of the metabolites and how does the toxicity compare to the parent (less, the same or greater than the parent)? Are the metabolites to be considered for regulatory and risk assessment purposes?*

➔ *What are the strengths, limitations, and uncertainties of the aquatic data?*

➔ *What are the terrestrial measures of effect data that specifically characterize the aquatic assessment endpoint(s) previously identified? (e.g., test results on two species of birds are being used to represent the toxicity to all bird species; further, the preliminary risk estimation will use the LD50 of the most sensitive species)*

➔ *If extrapolations are used, how appropriate are they? (.e.g., acute to chronic; extrapolations from lab to field; extrapolations from single species laboratory data to other trophic levels or indirect effects)*

➔ *What are the toxicity values (range, if appropriate), slopes, and confidence intervals, for the species/representative group chosen for the assessment?*

➔ *If the toxicity data was analyzed or used in a distribution, explain why and how.*

➔ *Be sure to identify the most sensitive species for each endpoint, the specific effect observed for each NOEC, any secondary effects, potential food source impacts.*

➔ *What is that adequacy and quality of the data (from both a scientific and regulatory perspective)?*

➔ *What are any data gaps and value of additional information to the risk assessment?*
➔ *What is the relationship of the species tested to species and habitat where exposure is likely to occur?*
➔ *What is the relevance of field study and/or monitoring data and incidence data?*
➔ *What is a synthesized interpretation of all available data including lab and field?*

5.1.3. Linking Measures of Effect to Assessment Endpoints

➔ *What organisms/groups of organisms/populations/ communities/ecosystems, etc. are affected?*
➔ *What is the nature of the effect(s)?*
➔ *Where appropriate, what is the time scale for recovery?*
➔ *What causal information links the pesticide with any observed effects?*
➔ *How do changes in measures of effects data relate to changes in assessment endpoints?*
➔ *What is the uncertainty associated with the analysis?*

5.2. Characterization of Exposure

Key exposure information from the Exposure Assessment Section in the Appendix should be identified and highlighted in this section. The information in the appendix should **not be reiterated in its entirety**.

5.2.1. Environmental Fate Characterization

➔ *The following information should be presented: identification of primary dissipation pathways; relative magnitude; assumptions; limitations of analysis; confidence (data quality, quantity, appropriateness); discussion of potential for off-site movement (runoff, drift, leaching, volatilization); geographic variation; effects of management practices; value of additional data.*

➔ *In addition to the pesticide, are there water degradates of toxicological concern? Is the pesticide and/or its major degradates persistent and/or mobile? Is there an expectation that residues of the pesticide and/or its major degradates will occur in surface or ground water and why or why not?*

5.2.2. Aquatic Exposure Characterization (Model Estimates)

➔ *What is the quality of the data, data gaps, uncertainties, and strengths, and limitations of the data used for the surface and ground water assessments, and models?*

➔ *The following quantitative aspects of the assessment should be presented: EEC or extent of leaching calculations (GENEEC and PRZM/EXAMS); interpretation of EEC or extent of leaching calculations; assumptions; limitations; confidence; frequency of occurrence; spatial and temporal variability; areal extent, timing; duration; magnitude; level of analysis (eg. screening); value of additional data; model outputs (as appendices); any field studies, monitoring results, and any available geographic information systems analysis.*

➔ *This section should provide a synthesized interpretation of all available data including modelling, monitoring, field studies (runoff), and geographic information systems analysis.*

➔ *What is the frequency and timing of the exposure? Duration? When does it occur in relation to critical organism life cycles or ecosystem events?*

➔ *Does the pesticide bioaccumulate?*

➔ *What is the spatial scale of exposure? Is the extent or influence of the stressor local, regional, global, habitat-specific, or ecosystemwide?*

➔ *What is the distribution of the pesticide? How does it move through the environment?*

➔ *How were EEC values derived (models, monitoring data)?*

➔ *If monitoring data were available, what were the sources and what is the level of confidence EFED has in the data?*
➔ *Can the monitoring data be used quantitatively in the risk assessment, why or why not?*
➔ *In the absence of adequate monitoring data, what models and inputs were used to estimate residues in drinking water from ground and surface water sources?*
➔ *What are the limitations of those data?*
➔ *How should the EEC values be used in the risk assessment?*

5.2.3. Terrestrial Exposure Characterization (Model Estimates)

➔ *What is the frequency and timing of the exposure? Duration? When does it occur in relation to critical organism life cycles or ecosystem events?*
➔ *Does the pesticide bioaccumulate?*
➔ *What is the spatial scale of exposure? Is the extent or influence of the stressor local, regional, global, habitat-specific, or ecosystemwide?*
➔ *What is the distribution of the pesticide? How does it move through the environment?*
➔ *What is the quality of the data, data gaps, uncertainties, and strengths, and limitations of the data used for the FATE or other models?*
➔ *The following information should be presented and discussed: EEC calculations; discussion of all models used, e.g., Fletcher et al/Kenaga; interpretation of EEC calculations; assumptions; limitations; confidence; recurrence frequency; spatial variability; timing; duration; magnitude; level of analysis (eg. screening); value of additional data.*
➔ *Reconcile (explain) relationship and interpretation of all available data, any relevant field residue data or field study (terrestrial) information.*

6.0 Risk Characterization [See Attachments A, B, and C for examples]

Environmental risk characterization is the summarizing step of risk assessment. It is the integration of the fate and transport evaluation and exposure characterization with the ecological effects characterization into a comprehensive, scientifically defensible description of the extent and potential risk to the environmental from pesticide use. Key components of the risk characterization discuss the ecological significance of the adverse effects, including consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery; strengths, limitations, and uncertainties of the risk assessment; and a comparative environmental risk analysis with other pesticides. The risk characterization should provide a clear, concise, and

informative discussion on the scientific rationale in the assessment of potential risk from a pesticide for decision-makers and other interested parties. In addition, the Division supports the Health Effects Division in their human health risk characterizations by describing distributions of pesticide concentrations in drinking water.

6.1. Risk Estimation - Integration of Exposure and Effects

6.1.1. Screening Level of Risk Characterization

➔ *Risk quotients should be calculated and compared to levels of concern in each sections below (6.1.2 - 6.1.4). Also include a discussion of the appropriate screening level models(s) used to calculate the EEC's. When risk quotients exceed the levels of concern, the magnitude of the exceedence should be expressed (in terms of whole numbers). The discussion should be framed in terms of potential risk.*

6.1.2. Aquatic Risk Quotients and Comparison to LOCs

6.1.3. Terrestrial Risk Quotients and Comparison to LOCs

6.1.4. Risks to Endangered Species

6.2. Risk Refinement [See Attachments A, B and C for examples]

➔ *Refined Risk Evaluations for screening level risks described in sections 6.1.1. to 6.1.4 above may be triggered because the RQ exceeds the LOC's (Levels Of Concern). Both the Exposure and the eco-toxicity may be refined. Probabilistic models, Tier 2 or Tier 3, field data, and monitoring data to assess range of potential exposure. Similarity, further analysis of the eco-toxicity data, field data, incident data, and effects monitoring data need be considered. For Risk quotients that continue to exceed the levels of concern, the magnitude of the exceedance should be expressed (in terms of whole numbers). The discussion should continue to be framed in terms of potential risk.*

6.2.1. Refined Level of Risk Characterization

6.2.2. Probabilistic Approaches Incorporating Variability in Exposure and/or Effects

6.2.3. Application of Population Models

6.3. Risk Description [See Attachments A, B and C for examples]

6.3.1. Lines of Evidence

➔ *What are the Strengths, Limitations and Uncertainties of the Assessment? The probability of risk needs to be clearly stated in the context of the overall risk characterization. Discuss the impacts of the strengths, limitations and uncertainties of the*

exposure and ecological effects characterization in the context of the overall environmental risk assessment, including the exposure and the effects values used in the quotient calculations, the ground water and surface water estimations. Discuss the additional data available (supporting and conflicting) to further refine the risk estimation, including field studies, incident data, monitoring data, modelling data, etc. Discuss how this may modify the risk evaluation. These discussions should address:
(1) the sufficiency and quality of the additional data;
(2) the strengths of the causal relationships between the lab and field data;
(3) identification of any additional analyses that are needed to enhance the risk characterization;
➔ *What are the Magnitude and Frequency of the Adverse Effects? Examine the dissipation characteristics of the pesticide and discuss how this might impact the magnitude and frequency of the risk. In addition, it should include the LOC exceedance, number and extent of incidents or field studies with effects, use rates, number of applications, types of applications (ground, aerial, air blast, ULV, irrigation, etc.) number of crops, number of acres treated, timing of the applications. The magnitude and frequency of the effect will also depend on its ecological context, i.e., how the effect(s) might impact populations, communities, ecosystems.*
➔ *What are the Spatial Patterns of Adverse Effects? Examine the dissipation characteristics of the pesticide and discuss how this might impact the spatial pattern of adverse effects. In addition, it should include a discussion of the likelihood of exposure to species most at risk based on geography of use area(s), distance to wetlands, rivers, streams, estuaries, National/State parks, wildlife refuges, breeding grounds and sanctuaries. The extent of the area where the chemical is used is a primary consideration when evaluating the spatial pattern of effects. A chemical used over a larger area has a greater potential to affect more organisms than one confined to a small area. However, a chemical that adversely affects a small area can have more major effects if those areas provide critical resources for certain species. In addition, adverse effects to a resource that is small in scale may have a small spatial effect but may represent a significant degradation of the resource because of its overall scarcity. This section will include use of GIS analysis when and where the time and resources are provided.*
➔ *What are the Temporal Pattern of Adverse Effects? Examine the dissipation characteristics of the pesticide and discuss how this might impact the temporal pattern of adverse effects. The duration of adverse effects based on the pesticide's environmental persistence, use--major vs. minor, number of applications, application method; also pattern of adverse effects, should be discussed. Timing of exposure in relationship to critical life stages of exposed organisms should also be discussed.*

6.3.2. Comparative Risk Analysis [See Attachment D for an example]

➔ *All major risk assessments should include a comparative analysis of the risk estimates for the pesticide and its major uses to pesticide alternatives. This is usually based on the screening level Risk quotient/LOC analysis for the pesticide being assessed and the alternatives identified by BEAD for comparison. The simple multi-attribute rating technique or SMART can be used to perform this comparison [Go to* http://www.epa.gov/pesticides/rodenticidecluster/, *click on "View this docket", and select OPP-2002-0049-0002 Potential Risks of Nine Rodenticides to Birds and Nonteaget Mammals: A Comparative Approach, for an explanation of the technique and its application. In addition, see Goodwin, P. and G. Wright. 1998. Decision analysis for management judgement, 2nd Ed. John Wiley & Sons, England. pp.454]. There should be a discussion of the best interpretation of these results.*

6.3.3. Risk Conclusions - Reporting Risks

➔ *Should include a statement on the likelihood of occurrence and consequences of the adverse effects based on weight of evidence and professional judgement. Where data permit, probability should be addressed.*

➔ *Are the risks sufficiently well defined (and data gaps small enough) to support a risk management decision?*

➔ *Were the effects and exposure adequately characterized?*

➔ *Was the risk adequately characterized?*

➔ *What adverse effects are likely to occur?*

➔ *How adverse are the adverse effects?*

➔ *How likely is it that adverse effects will occur? What are the uncertainties?*

➔ *When and where do the adverse effects occur?*

➔ *How confident are you in the conclusions of the risk assessment?*

➔ *What are the critical data gaps? Will these data be available in the near future to fill these gaps? How should the missing data affect the regulatory decision?*

➔ *Are additional refinement in the ecological risk assessment required?*

7.0 Relating Ecological Information to Risk Management Decisions

7.1. Discuss Risk Mitigation

Assuming that the ecological risks have been sufficiently defined and characterized to support a risk management decision, the risk managers may deem the scientific and societal risks of a pesticide's use(s) to be unacceptable. In that case, the risk management decision will likely include a risk reduction component. Risk reduction involves

implementation of remedial or mitigation measures to reduce or eliminate unacceptable source contamination and/or adverse environmental impact. Mitigation measures should reflect the best possible non-point control practices, technologies, processes, or other alternatives which will result in the greatest achievable reduction in the availability of a pesticide to nontarget organisms. [See "Preliminary Recommendations on Developing Risk Reduction Strategies and Monitoring Programs," prepared by the Environmental Fate and Effects Division, November 1993]

7.1.1 Risk Mitigation Measures

➔ *Can source control measures such as reduction in the application rate, reduction in the number of applications, or increasing the application interval, prescription use, and/or elimination of specific use, formulations, application methods, etc be implemented for the pesticide use(s)? Can the risk reduction(s) be quantified?*

➔ *Will educational programs help to reduce the risk(s)?*

➔ *What about imposing production caps, limiting the crops on the label, limiting the total number of acres treated, implementing state management plans?*

➔ *For surface water sources, will vegetative buffer zones help? Vegetative filter strips? Constructed wetlands? Detention ponds/other water holding areas?*

➔ *For terrestrial risk concerns, will changes in the formulation or application methods reduce the risk(s)? Can the reduction(s) be quantified?*

➔ *Can habitat quality be ranked, leading to rational use restrictions by geographic area, time of the year?*

➔ *Should monitoring be considered? Can a monitoring program help to quantify and/or better understand the existing the risk(s), and/or help to evaluate the evaluate proposed monitoring measures?*

➔ *Should compensatory mitigation measures be considered?*